SCHEMA – PROTOCOL O1

TITLE: Clinical trial to compare specified antiretroviral (ARV) regimens for the treatment of HIV infection.

DESIGN: Phase III, randomized, open-label clinical trial.

POPULATION: HIV-infected persons meeting criteria for ARV treatment.

DURATION: Study participants will be followed at least one year.

PRIMARY OBJECTIVE(S): To determine the efficacy, safety and tolerability of the treatment regimens.

SECONDARY OBJECTIVES

1. To compare CD4+ and CD8+ cell count responses
2. To compare patterns of resistance
3. To compare the effects of the regimens on metabolic parameters
4. To assess the effects of hepatitis B and C infection on efficacy and safety
5. To assess adherence to the antiretroviral regimens
6. To assess the impact of the regimens on quality of life

SCHEDULE OF EVALUATIONS FOR THE FIRST TWELVE MONTHS – PROTOCOL O1

	SCREENING & ENROLLMENT		STUDY WEEKS											
EVALUATIONS	**S**	**E**	**2**	**4**	**6**	**8**	**12**	**16**	**20**	**24**	**32**	**40**	**48**	**d/c or Failure**
Obtain Informed Consent	X													
History and Physical Exam	X	X	X	X		X	X	X	X	X	X	X	X	X
Hematology	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Chemistry panel	X	X					X			X			X	X
Metabolic panel for fats and glucose	X	X					X			X			X	X
Hepatitis B and C Serologies	X	X												
EKG	X													
Urinalysis	X	X												
Pregnancy Test	X	X												
CD4+ and CD8+ cell counts	X	X		X		X		X		X	X	X	X	X
HIV-1 RNA	2 values	X	X	X		X	X	X	X	X	X	X	X	2 values
Genotyping/Phenotyping		X												X
Specimen storage: serum		X						X			X		X	X
Specimen storage: plasma		X						X			X		X	X
Specimen storage: PBMC’s		X						X			X		X	X
Questionnaires		X					X			X			X	X